IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE,	:	**CIVIL ACTION**
	:	
Plaintiff,	:	
	:	
v.	:	**NO. 07-348**
	:	
MCNEIL-PPC, INC.; MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a division of MCNEIL-PPC, INC.; MCNEIL CONSUMER HEALTHCARE, a division of MCNEIL PPC, INC.; JOHNSON & JOHNSON, INC.; and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC,	:	
	:	
Defendants.	:	

DuBOIS, J. **May 3, 2011**

M E M O R A N D U M

I. INTRODUCTION

Plaintiff Kiley Wolfe alleges in this action that Children's Motrin[1] manufactured and marketed by defendants caused her to develop serious, life-altering illnesses. Presently before the Court are nine Daubert[2] motions – three filed by plaintiff and six by defendants – to exclude or limit the proposed testimony of a total of eleven proposed expert witnesses. For the reasons that follow, the Court denies four of defendants' motions and all three of plaintiffs' motions. The

[1] Children's Motrin is a brand-name version of the over-the-counter ("OTC") drug ibuprofen.

[2] Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993)

remaining two motions – defendants' motion to exclude the testimony of Drs. Laura Bix and Marvin Goldberg and their motion to exclude the testimony of Dr. George M. Samaras – are granted in part and denied in part.

II. BACKGROUND

By Memorandum and Order of March 30, 2011, the Court denied defendants' motion for summary judgment as to plaintiff's failure-to-warn claims and claim for punitive damages and granted the motion in all other respects. Wolfe v. McNeil-PPC, Inc., --- F. Supp. 2d ---, 2011 WL 1157927, at *12 (E.D. Pa. Mar. 30, 2011). The factual background of the case is set forth in the Memorandum of March 30, 2011, and will not be repeated in this Memorandum except as is necessary to explain the Court's rulings.

III. LEGAL STANDARD – FEDERAL RULE OF EVIDENCE 702

Federal Rule of Evidence ("Rule") 702 provides as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The "pathmarking" Supreme Court cases interpreting Rule 702 are Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993), and Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999). United States v. Mitchell, 365 F.3d 215, 234 (3d Cir. 2004). In Daubert, the Supreme Court held that "[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Daubert, 509 U.S. at 592. In Kumho

Tire, the Supreme Court made clear that the Daubert gatekeeping function extends beyond scientific testimony to testimony based on "technical" and "other specialized" knowledge. 526 U.S. at 141.

Under Daubert, courts must address a "trilogy of restrictions" before permitting the admission of expert testimony: qualification, reliability and fit. Schneider ex rel. Est. of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003); see also Elcock v. Kmart Corp., 233 F.3d 734, 741 (3d Cir. 2000). The party offering the expert must prove each of these requirements by a preponderance of the evidence. In re TMI Litig., 193 F.3d 613, 663 (3d Cir. 1999).

A. Qualification

To qualify as an expert, "Rule 702 requires the witness to have 'specialized knowledge' regarding the area of testimony." Betterbox Commc'ns Ltd. v. BB Techs., Inc., 300 F.3d 325, 335 (3d Cir. 2002) (quoting Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998)). The Third Circuit has instructed courts to interpret the qualification requirement "liberally" and not to insist on a certain kind of degree or background when evaluating the qualifications of an expert. See Waldorf, 142 F.3d at 625. "The language of Rule 702 and the accompanying advisory committee notes make clear that various kinds of 'knowledge, skill, experience, training, or education,' qualify an expert as such." In re Paoli R.R. Yard PCB Litig., 916 F.2d 829, 855 (3d Cir. 1990) (quoting Fed. R. Evid. 702) ("Paoli I").

Moreover, "[t]his liberal policy of admissibility extends to the substantive as well as the formal qualifications of experts." Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008). Thus, "it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have

the specialization that the court considers most appropriate." Id. (quoting Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir.1996)).

B. Reliability

The reliability requirement of Daubert "means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994) ("Paoli II") (quoting Daubert, 509 U.S. at 590). In Kumho Tire, the Supreme Court held that the Daubert test of reliability is "flexible" and that "the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." 526 U.S. at 141-42 (emphasis omitted). In determining whether the reliability requirement is met, courts examine the following factors where appropriate:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Mitchell, 365 F.3d at 235 (citing Paoli II, 35 F.3d at 742 n.8). These factors are neither exhaustive nor applicable in every case. Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 806-07 (3d Cir. 1997).

Under the Daubert reliability prong, parties "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." Paoli II, 35 F.3d at

744 (emphasis omitted). "The evidentiary requirement of reliability is lower than the merits standard of correctness." Id. "As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process – competing expert testimony and active cross-examination – rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." Mitchell, 365 F.3d at 244 (quoting Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 85 (1st Cir.1998)).

C. Fit

For expert testimony to meet the Daubert "fit" requirement, it must "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. "This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." Daubert, 509 U.S. at 591 (citations and internal quotation marks omitted). "'Fit' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." Id.

IV. DEFENDANTS' DAUBERT MOTIONS

With those standards in mind, the Court turns first to defendants' Daubert motions. Defendants have filed six motions addressing the proposed testimony of eight experts. The Court will address each motion in turn.

A. Motions to Exclude Testimony of Drs. Moshe Arditi, Talal Chatila and Philip Rosenthal[3]

Defendants seek to exclude the testimony of three of plaintiff's proposed causation

[3] Because these three motions raise largely the same legal issues, the Court will address them in the same section.

experts: Dr. Moshe Arditi, Dr. Talal Chatila and Dr. Philip Rosenthal. The Court concludes that all three experts are qualified under Daubert and Rule 702 and denies defendants' motions.

Dr. Arditi is the Director of Pediatric Infectious Diseases and Immunology at Cedars Sinai Medical Center in Los Angeles. He also practices at Cedars Sinai and is a professor of pediatrics at the University of California, Los Angeles ("UCLA"). His proposed testimony is that the testing performed on plaintiff that failed to find a viral or bacterial cause for her Stevens-Johnson Syndrome ("SJS")[4] was "very systematic" and "thorough." (Arditi Report at 4.) Based on this opinion, he concludes "to a reasonable degree of medical certainty" that plaintiff's SJS with Vanishing Bile Duct Syndrome ("VBDS")[5] was not caused by a viral or bacterial infection but was instead "most likely drug-induced." (Id.)

Dr. Chatila, like Dr. Arditi, is a professor of pediatrics at UCLA. He heads the Division of Pediatric Immunology, Allergy and Rheumatology at that school. He is prepared to testify, "to a reasonable degree of medical certainty," that plaintiff's SJS and VBDS were caused by the Children's Motrin she ingested. (Chatila Report at 4.)

Dr. Rosenthal is the Director of Pediatric Hepatology and the Medical Director of the Pediatric Liver Transplant Program at the University of California, San Francisco. He has opined that plaintiff developed SJS and VBDS (leading to a liver transplant) because she took ibuprofen.

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[4] SJS is "a rare, serious disorder in which your skin and mucous membranes react severely to a medication or infection." Mayo Clinic, Stevens-Johnson Syndrome, http://www.mayoclinic.com/health/stevens-johnson-syndrome/DS00940 (last visited Apr. 25, 2011). The disease is sometimes fatal. Dorland's Illustrated Medical Dictionary 1833 (30th ed. 2003).

[5] VBDS is a condition where the bile ducts in the liver are destroyed. (See Pl.'s Resp. to Defs.' Mot. for Summ. J., Ex. C at 14:20-21.)

(Rosenthal Report at 4.)

The defendants challenge the qualifications of these three experts and the reliability of their methodology. The Court finds defendants' arguments unpersuasive.

1. *Qualifications*

As noted above, Dr. Arditi practices medicine at Cedars Sinai in Los Angeles. He specializes in pediatric infectious diseases and is a professor of pediatrics at UCLA. He has authored more than 80 peer-reviewed articles, which have been published in such journals as the New England Journal of Medicine and Pediatrics. (See Pl.'s Opp'n to Defs.' Mot. to Exclude Arditi, Ex. C.) He has treated "many" patients with SJS and related ailments. (Arditi Dep. at 21.)

Dr. Chatila's work focuses on immunological and allergic diseases. (Chatila Report at 1.) He has authored more than 100 peer-reviewed articles, which have been published in an array of reputable professional journals. (See Pl.'s Opp'n to Defs.' Mot. to Exclude Chatila, Ex. E.) Over the course of his career, he has helped care for patients with SJS and related illnesses. (Chatila Dep. at 29.)

Dr. Rosenthal has 30 years' experience as "an actively practicing pediatric gastroenterologist." (Rosenthal Report at 1.) He has published more than 100 peer-reviewed journal articles. (See Pl.'s Opp'n to Defs.' Mot. to Exclude Rosenthal, Ex. E.) He has helped treat three patients with SJS over the course of his career. (Id., Ex. B at 14-16.) He has seen "lots" of patients with liver disease. (Id., Ex. E at 28.)

Defendants contend that Dr. Arditi is not qualified to opine on the cause of plaintiff's SJS and VBDS because he is "self-admittedly not an SJS expert" and "not an expert in the liver or

diseases of the liver." (Defs.' Mot. to Exclude Arditi at 8-9.) They argue that Dr. Chatila is not qualified to opine on the cause of plaintiff's SJS and VBDS because he has never published work on SJS or drug reactions, never in his practice determined the cause of a patient's SJS and is not an expert on liver disease. (Defs.' Mot. to Exclude Chatila at 8, 11.) Finally, they assert that Dr. Rosenthal is not qualified to opine on the cause of plaintiff's SJS and VBDS because he has never determined the cause of a plaintiff's SJS, admits he is not an expert in SJS, has never published any work regarding SJS and has never treated a patient who had both liver disease and SJS. (Id. at 5-6, 8-9.)

Under Daubert, however, an expert's base of knowledge need not be as specialized as defendants urge. As the Third Circuit has held, "it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." Pineda, 520 F.3d at 244 (quoting Holbrook, 80 F.3d at 782). That Dr. Arditi has never conducted his own research on the causes of SJS or VBDS and does not consider himself an expert in the two diseases "goes to credibility and weight, not admissibility." Id. The same analysis applies to the claimed deficiencies in the qualifications of Drs. Chatila and Rosenthal. In sum, the three doctors satisfy Daubert's "liberal" qualifications standard.

2. *Reliability*

In reaching his conclusions, Dr. Arditi reviewed a panoply of records from this case, as well as several articles that discuss the relationship among ibuprofen, SJS and VBDS. He concluded that the tests performed on plaintiff ruled out known viral or bacterial causes and that, therefore, her ailments were most likely drug-induced. This method of determining causation based on a

process of elimination of other potential causes is known as a differential diagnosis. See Stedman's Medical Dictionary 531 (28th ed. 2006). Drs. Rosenthal and Chatila also performed differential diagnoses. A proper differential diagnosis is a reliable scientific method under Daubert. See Heller v. Shaw Indus., Inc., 167 F.3d 146, 154-55 (3d Cir. 1999). That is so even where the expert never performed a physical examination of the injured party. Kannankeril, 128 F.3d at 807.

Defendants assert that the three doctors' methodology is unreliable because (1) they did not rule out all potential viruses – for example, because there are unknown viruses and viruses for which no tests are available – and (2) the literature they reviewed on SJS and VBDS consisted primarily of only two or three case reports. Neither argument is persuasive.

First, in performing a differential diagnosis, an expert is only required to rule out "[o]bvious alternative causes." Heller, 167 F.3d at 156 (citation omitted). "A medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of plaintiff's illness." Id. Defendants will, of course, be able to cross-examine the three doctors about potential causes they did not exclude. But their inability to rule out all possible causes before rendering their diagnoses does not render their opinions unreliable under Daubert.

Second, case studies are reports of clinical events involving only one or a few people. Reference Manual on Scientific Evidence 474 (2d ed. 2000). Because they lack the controls of more rigorous studies, such reports "must be regarded with caution." Id. at 475. However, "such studies may be carefully considered in light of other information available." Id.; see Heller, 167 F.3d at 154 ("[W]e do not believe that Daubert . . . require[s] a physician to rely on definitive published studies before concluding that exposure to a particular object or chemical was the most

likely cause of a plaintiff's illness."); Deutsch v. Novartis Pharm. Corp., --- F. Supp. 2d ---, 2011 WL 790702, at *54 (E.D.N.Y. Mar. 8, 2011) ("Even if case reports on their own are not reliable evidence of causation, they do contribute to the reliability of a causation determination.").

In this case, the three doctors did not solely rely on case reports in forming their opinions on causation but used them to supplement their extensive review of plaintiff's medical records and deposition testimony of plaintiff's treating physicians. As with defendants' other objections, the three doctors' use of case studies in reaching their conclusion affects only the weight to be given their testimony, not its admissibility. Thus, the proposed testimony of the three doctors is based on sufficiently reliable methods.

3. *Fit*

The three doctors' testimony clearly will help the trier of fact determine a fact in issue. The testimony addresses one of the central issues in the case: whether the ingestion of Children's Motrin caused plaintiff to develop SJS and VBDS. Thus, the three doctors' proposed testimony satisfies the third prong of Daubert.

4. *Conclusion*

The Court concludes that the proffered testimony of Drs. Arditi, Chatila and Rosenthal satisfies the "trilogy of restrictions" imposed by Rule 702 and Daubert. Accordingly, defendants' motions to exclude their testimony are denied.[6]

[6] Defendants also object that the causation testimony of the three doctors is unduly cumulative of each other's testimony and of the testimony of the six other experts plaintiff has designated to opine on causation. (See Mot. to Exclude Arditi at 5 n.2.) Such an argument is premature, as plaintiff has yet to identify which of her causation experts she intends to call at trial. The Court, however, is highly skeptical that plaintiff can present nine causation witnesses without the probative value of such testimony becoming substantially outweighed by "the needless presentation of cumulative evidence." Fed. R. Evid. 403. This issue will be addressed

B. Motion to Exclude Testimony of Lorraine Buchanan and Limit Testimony of Royal Bunin

On the question of damages, plaintiff offers Lorraine E. Buchanan, R.N. as a life care planner to opine on the cost of future care for plaintiff and economist Royal Bunin, M.B.A. to testify about future damages generally. Defendants attack the reliability of Buchanan's methods and seek to limit Bunin's testimony to the extent it relies on Buchanan's work. The Court finds Buchanan's methodology sufficiently reliable and accordingly denies the motion.

1. *Qualifications*

Buchanan is a registered nurse who has 36 years of experience in rehabilitation nursing and 20 years of experience creating life care plans. (Buchanan Dep. at 227-28.) She is clearly qualified by experience to create life care plans, and defendants do not argue to the contrary.

2. *Reliability*

Defendants do, however, contest whether Buchanan's methodology is reliable. They raise three arguments in support of their position: (1) Buchanan's life care plan is based on incomplete information; (2) Buchanan utilized the input of a co-worker inappropriately in crafting the plan; and (3) the plan aims to provide a level of care for plaintiff that is inappropriately high. All of these arguments are unavailing.

First, defendants contend that Buchanan's report is the product of incomplete information because she never spoke to any of plaintiff's treating physicians, did not discuss SJS with any health care providers, and did not consult any learned treatise or text to educate herself about SJS. (Defs.' Mot. to Exclude Buchanan at 7.) Buchanan did, however, review plaintiff's medical records, consult with several physicians (who are admittedly plaintiff's retained experts)

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at the final pretrial conference or at an earlier stage of the proceeding.

and interview the plaintiff. (See Buchanan Plan at 3-5.) Her plan consistently references factual support for her conclusions. (See, e.g., Id. at 11 (recommendation of OB/GYN specialist that plaintiff receive psychological counseling because her condition makes it unsafe for her to try to have children of her own); Id. at 17 (recommendation of neuropsychologist that plaintiff be provided the services of a home aide 10 hours a day).) That she did not consult certain sources that defendants deem relevant goes only to the weight of her testimony, not its admissibility.

McNamara v. Kmart Corp., 380 F. App'x 148 (3d Cir. 2010), which defendants assert supports their position, is inapposite. In McNamara, the Third Circuit ruled that the district court did not abuse its discretion when it did not allow the plaintiff to present expert testimony regarding future life-care needs. Id. at 152. The testimony was excluded because "there was no support in [the expert's] report for such expenses." Id. (emphasis added). By contrast, as detailed above, there is ample support in Buchanan's report (as amplified by her deposition testimony) for her opinions. Thus, the evidentiary basis for Buchanan's opinion is more than sufficient to satisfy Daubert.

Second, defendants allege that Buchanan's testimony should be barred because her conclusions are based partly on conversations she had with her colleague, Carolyn Uveges. Defendants state, "Buchanan has no greater right to rely on the subjective views of her employee Uveges than those of any person she meets during a casual encounter." (Defs.' Mot. to Exclude Buchanan at 6.) This argument is similarly unpersuasive. Uveges is a certified nurse life care planner who has worked for three years at the same company as Buchanan. (Buchanan Dep. at 53, 30.) It is Buchanan's "customary practice" to show her reports to Uveges before submitting them to make sure the formatting, grammar and math in the reports are correct and to see if

Uveges agrees with Buchanan's conclusions. (Id. at 31-34.) She did that in this case. Buchanan was clear, however, that she was the "ultimate author" of the report. (Id. at 33-34.) It would be strange, indeed, if the mere fact that an expert consulted with a similarly qualified colleague to test her theories rendered her conclusions less reliable. That Buchanan does not have a record of the exact changes Uveges proposed (and which were adopted) does not make her method unreliable, although it is a perfectly legitimate ground for cross-examination.

Third, defendants contend that Buchanan's plan aims to provide an inappropriately generous level of care that neither plaintiff nor her treating physicians requested. (Defs.' Motion to Exclude Buchanan at 8-9.) In particular, defendants challenge the need for plaintiff to have a home aide with her 10 hours a day for the rest of her life, when plaintiff has never requested such assistance. (Buchanan Dep. at 243.) Defendants allege that "[Buchanan] simply pulled her very expensive opinion from thin air." (Defs.' Mot. to Exclude Buchanan at 2.)

This is simply not the case. Buchanan based her recommendation for a home aide on the advice of neuropsychologist Dr. Bruce Jones, as well as her own evaluation of plaintiff's living situation. Buchanan noted that plaintiff's current roommate, Katelyn Williamson, will likely move when she graduates from college this year. (Buchanan Report at 17.) Williamson drives plaintiff to appointments and calls for assistance when needed. (Id. at 12.) Plaintiff's father also lives nearby and helps with picking up medications, driving her to appointments and checking up on her. (Id.) Buchanan explained, however, that "[i]t is not the practice of any life care planner that I know of to expect family to step in and do what she can no longer do." (Buchanan Dep. at 237.) Given that explanation – and given the likelihood that plaintiff's parents will predecease her – it is eminently reasonable for Buchanan to include the home aide in her report, regardless of

whether plaintiff requested such assistance.

Of course, defendants will be free to cross-examine Buchanan on her decision to include services that plaintiff did not request or that might duplicate assistance she presently receives. So long as Buchanan has a reliable basis for her recommendations, however, it matters not under Daubert whether plaintiff or her physicians concur that such care is necessary.

In sum, Buchanan's report is the result of the application of her expertise and experience to a sufficient factual base to permit her to express her expert opinions. Thus, the Court concludes that her proposed testimony is based on reliable methodology.

3. *Fit*

Buchanan's proposed testimony relates to a central issue – damages – that will be contested at trial. Thus, it satisfies Daubert's fit requirement.

4. *Rule 403*

Defendants argue that, even if Buchanan's proposed testimony is admissible, it should be excluded under Federal Rule of Evidence ("Rule") 403 because its probative value is substantially outweighed by its danger to cause unfair prejudice. Defendants have failed to proffer any specific reason why the Court should find a great danger of unfair prejudice in Buchanan's proposed testimony. Thus, their attempt to have it excluded under Rule 403 is denied.

5. *Conclusion*

The Court concludes that Buchanan's proposed testimony is admissible under Rules 702 and 403. As defendants only seek to have Bunin's proffered testimony excluded to the extent it relies on Buchanan's work, the Court also concludes that there is no reason for Bunin's testimony to be limited. The motion to exclude Buchanan's testimony and limit Bunin's

testimony is denied.

C. Motion to Exclude Testimony of Drs. Marvin E. Goldberg and Laura Bix[7]

Defendants have also moved to exclude the testimony of Dr. Marvin E. Goldberg, a marketing expert, and Dr. Laura Bix, a packaging and labeling expert. The motion is granted as to Dr. Goldberg and granted in part and denied in part as to Dr. Bix.

1. *Dr. Goldberg*

Dr. Goldberg is a professor of marketing at Penn State University and the former chairman of the department of marketing at the school. Dr. Goldberg is prepared to testify that:

- Defendant McNeil-PPC, Inc. ("McNeil") did not adequately communicate to consumers and health care providers the risks associated with Children's Motrin. (Goldberg Report at 2.0, 3.0.)
- McNeil "had the responsibility of developing a more effective warning regarding the symptoms and potentially deadly consequences of SJS and its association with Children's Motrin." (Id. at 4.0.)
- McNeil should have communicated that warning through all available advertising and promotional channels. (Id. at 4.7.)
- McNeil had "distort[ed]" corporate priorities, with marketing playing a "critical role in shaping McNeil's agenda for its medical/clinical studies." (Id. at 5.0.)
- McNeil was "negligent" for failing to research how consumers would respond to labeling telling them to call a doctor if new symptoms arose. (Id. at 13.0.)

Defendants argue, inter alia, that Dr. Goldberg makes inappropriate legal conclusions, offers testimony that does not fit the case and has not relied on reliable methodology in forming his judgment. The Court agrees and grants defendants' motion as to Dr. Goldberg.

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[7] Defendants initially also included in this motion a request to exclude the testimony of Dr. George M. Samaras. At the time, defendants had yet to depose Dr. Samaras. After the Court granted the parties additional time to complete expert discovery and file further Daubert motions, defendants deposed Dr. Samaras and filed a separate motion to exclude his testimony. Thus, the portion of this motion that addressed Dr. Samaras's testimony is denied as moot. Defendants' separate motion to exclude Dr. Samaras's testimony is discussed in Section IV.D, infra.

First, to the extent Dr. Goldberg plans to testify that McNeil behaved negligently in the conduct of its business, such testimony constitutes an improper legal opinion. Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006) ("Although Federal Rule of Evidence 704 permits an expert witness to give expert testimony that embraces an ultimate issue to be decided by the trier of fact, an expert witness is prohibited from rendering a legal opinion." (citation and internal quotation marks omitted)). It will be the role of the jury, not Dr. Goldberg, to determine if McNeil acted negligently.

Second, none of Dr. Goldberg's opinions regarding marketing of Children's Motrin fit the case. The Court has already granted defendants' motion for summary judgment on plaintiff's negligent marketing claim because the tort is not recognized in Pennsylvania.[8] Moreover, there is no evidence in the record that any party – the plaintiff, her mother or her pediatrician – ever saw Children's Motrin advertising or relied on such advertising in making decisions about whether plaintiff should ingest the product.

Third, Dr. Goldberg's opinions about McNeil's "responsibility" to develop a better warning for Children's Motrin and better communicate the risks of their product are not based on reliable methodology. In his deposition testimony, Dr. Goldberg cites as support for his position the Supreme Court's opinion in Wyeth v. Levine, 555 U.S. 555 (2009); "simple common sense and ethical responsibility"; "an understanding that society has"; and "how our free market operates." (Goldberg Dep. at 150-154.) Plaintiff argues that the principles Dr. Goldberg used in

[8] The Court notes that the Pennsylvania Supreme Court recently granted a petition for allowance of appeal in a case that, inter alia, raises the question whether Pennsylvania would recognize a negligent marketing tort for prescription drugs. Lance v. Wyeth, --- A.3d ---, 2011 WL 874169, at *1 (Pa. Mar. 15, 2011). The Superior Court held that such an action was not cognizable. Lance v. Wyeth, 4 A.3d 160, 169 (Pa. Super. Ct. 2010).

coming to his conclusions are "well-known principles amongst individuals in Dr. Goldberg's field." (Pl.'s Resp. to Defs.' Mot. to Exclude Bix and Goldberg at 14.) This is irrelevant. Simply because Dr. Goldberg's subjective views of ethics are informed by well-known principles does not convert them into objective, reliable, scientific knowledge.

Finally, even if Dr. Goldberg's proposed testimony could satisfy Daubert, it would still be excluded under Rule 403. Whatever benefit could be derived from his opinions about McNeil's social responsibility and ethical obligations is vastly outweighed by the tendency of such testimony to encourage the jury to impose liability on an improper basis. See In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 545 (S.D.N.Y. 2004) ("Even assuming that the proposed ethics testimony were reliable and marginally relevant under Rule 702, it would be likely unfairly to prejudice and confuse the trier by introducing the 'experts'' opinions and rhetoric concerning ethics as alternative and improper grounds for decision on bases other than the pertinent legal standards.").

The Court concludes that Dr. Goldberg's proposed testimony does not satisfy Daubert's strictures and would not assist the jury in deciding this case. Accordingly, defendants' motion is granted as it pertains to his testimony.

2. *Dr. Bix*

Dr. Bix is an associate professor at Michigan State University's School of Packaging. (Bix Report at 2.) She intends to offer the following opinions:

- The warning on the Children's Motrin plaintiff ingested was inadequate because it lacked language that "suggested the serious nature of dermatologic events associated with ibuprofen" and did not instruct consumers to discontinue the drug if symptoms of SJS appeared. (Bix Report at 14.) This inadequacy prevented plaintiff's mother, Janet Leland, from understanding the risks of continuing to give the drug to her daughter and from knowing when to discontinue

administration of the drug. (Id. at 14.)

- The label on OTC Children's Motrin in 1996 was inadequate because it failed to list SJS as a possible reaction, even though the prescription label included such a warning. (Bix Dep. at 195, 199.)
- The FDA is understaffed and under-resourced. (Id. at 161.)

Defendants argue that Dr. Bix is not qualified to render her opinions and that they are the product of unreliable methodology. The Court agrees that some of Dr. Bix's opinions do not pass muster under Daubert but concludes that most of her testimony can be presented to the jury.

As an initial matter, Dr. Bix testified that the primary basis for her expert opinion that the FDA is understaffed and under-resourced is a video from the PBS show "Frontline" that she shows to one of her classes each year. (Id. at 160-161.) This is not a reliable, scientific basis for an expert opinion. Thus, that portion of the proposed testimony must be excluded.

On the other hand, Dr. Bix is qualified to opine on the substantive adequacy of the 1996 Children's Motrin warning, and her opinion is based on reliable methodology. As a packaging professor, Dr. Bix has extensive knowledge about how people understand the labels they read. Dr. Bix has published more than 40 peer-reviewed articles and four book chapters on that subject. (Bix Report at 1.) Her work has included an article that describes how people process information about OTC pain relievers. (Id.) She serves on the editorial board of four journals. (Id.)

In reaching her conclusions about the packaging in this case, Dr. Bix applied widely held theories – to which she has contributed – about how humans interact with packaging. In part, this theory holds that for information about risks to be effective, "[t]he consumer must be exposed to the risk related information. This may occur incidentally or because the consumer actively pursues the information." (Id. at 4.) The rubric Dr. Bix employed in this case has been

published and peer reviewed and meets the Daubert standard for reliability.[9]

Defendants posit essentially two arguments for why Dr. Bix's proposed testimony about the adequacy of the label should be excluded. First, defendants assert that Dr. Bix is unqualified to opine about whether a warning about SJS or its symptoms should have been included because she is not a doctor or SJS expert. Second, they note that Dr. Bix was unable to point in her deposition to any specific regulation or industry standard that McNeil violated in not including the same warnings on the prescription and OTC labels. Neither argument is persuasive.

First, it is true that Dr. Bix is unqualified to testify that ibuprofen causes SJS, and she will not be allowed to do so at trial. However, after reviewing substantial literature on the association between SJS and ibuprofen – particularly literature that discusses the importance of recognizing early symptoms and discontinuing use of the drug once symptoms are recognized – Dr. Bix concluded that the warning in this case was inadequate to communicate the nature of the risk. Based on her years of studying human interaction with packaging, she is qualified to make that determination. Moreover, there is nothing objectionable about Dr. Bix's reliance on literature from those outside her field to inform her judgment. See Fed. R. Evid. 703, Notes of Advisory Committee on Rules ("Thus a physician in his own practice bases his diagnosis on information from numerous sources and of considerable variety, including statements by patients and relatives, reports and opinions from nurses, technicians and other doctors, hospital records, and X rays."); see also In re FEMA Trailer Formaldehyde Prods. Liab. Litig., No. 07-1873, 2010 WL 1935876, at *1 (E.D. La. May 6, 2010) (admitting testimony from warnings expert that trailers

[9] Dr. Bix's testimony on the adequacy of the label fits this case because it is relevant to the question whether the packaging for the Children's Motrin plaintiff consumed should have included a stronger warning.

should have included cautions about danger of formaldehyde even though expert needed to rely on opinions of other experts to conclude that formaldehyde was toxic). Thus, Dr. Bix is qualified to render her opinion on the adequacy of the label, regardless of her lack of medical expertise.

Second, plaintiff does not argue that Dr. Bix should be allowed to opine that the OTC Children's Motrin label violated federal regulations because it omitted warnings that were included on the prescription label. Rather, Dr. Bix relied on the fact that McNeil included the SJS warning on the prescription product as evidence of the nature of the risk presented by ibuprofen and the resulting need for a similar warning on the OTC label. There is nothing inherently unreliable about Dr. Bix using the prescription label, in combination with the rest of the literature she reviewed, to reach her conclusions.[10]

In sum, the Court concludes that only Dr. Bix's proposed testimony about the funding and staffing levels of the FDA should be excluded. Defendants' motion related to Dr. Bix is denied in all other respects.

D. Motion to Exclude Testimony of Dr. George Samaras

Finally, plaintiff offers Dr. George M. Samaras as a human factors[11] and regulatory expert. Dr. Samaras is a physiologist and engineer with approximately two years' experience

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[10] The Court is aware that, under the learned intermediary doctrine, a prescription drug manufacturer's duty to warn is limited to providing adequate warnings for the prescribing physician and that prescription and OTC labeling are aimed at different audiences. See Rosci v. AcroMed, Inc., 669 A.2d 959, 969 (Pa. Super. Ct. 1995). Any differences in prescription and OTC labeling, however, go only to the weight to be given Dr. Bix's testimony and not its admissibility. Defendants will have ample opportunity to cross-examine Dr. Bix about whether and how she considered these differences in formulating her opinions.

[11] Human factors is "an applied science concerned with designing and arranging things people use so that the people and things interact most efficiently and safely." Merriam-Webster's Collegiate Dictionary 424 (11th ed. 2003).

working at the FDA and four years' experience at an FDA predecessor. He is also a certified professional ergonomist.[12] He proposes to present the following opinions:

- The ibuprofen plaintiff consumed "is dangerous and is known to cause catastrophic illnesses." (Samaras Report at 3.)
- Labeling of OTC Children's Motrin "was driven by McNeil's sales & marketing function, rather than by medical and scientific experts . . . ." (Id.)
- "The [FDA] seems consistently under-resourced." (Id. at 2.) In addition, "[t]here is very limited time for a reviewer to do any independent literature research and the reviewer relies heavily on the truthfulness, accuracy, and completeness of the materials and information supplied by the manufacturer." (Id.)
- The OTC Children's Motrin label should have included a warning by 1996 that "rare but catastrophic dermatological and hepatic diseases could occur" as a result of consuming the drug. (Samaras Dep. at 167:7-16.)
- With a better warning, plaintiff's mother "would have had the risks communicated to her and would not have continued administration of ibuprofen beyond the initial dose that her daughter regurgitated." (Samaras Report at 3.)

Defendants contend that Dr. Samaras is not qualified to give his opinions, that his opinions are not based on reliable methodology and that some of his opinions do not fit the case. As with Dr. Bix, the Court agrees with defendants that some of Dr. Samaras's opinions are inadmissible. However, much of his testimony does satisfy the standards of Rule 702 and Daubert. Accordingly, the Court grants defendants' motion in part and denies it in part.

1. *Qualifications*

As noted above, Dr. Samaras is a professional engineer who used to work at the FDA and now consults with "FDA-regulated medical device and pharmaceutical firms." (Id. at 2.) His work includes helping regulated entities develop product labeling and labeling validation studies

[12] Human factors is also known as ergonomics. Id.

and analyzing the results of such studies. (Id.)

Dr. Samaras has no expertise regarding disease causation and thus lacks the qualifications to opine about whether ibuprofen is, in fact, "dangerous" or "known to cause catastrophic illness." Thus, his opinion on this issue is beyond the scope of his qualifications and inadmissible.

As with Dr. Bix, however, Dr. Samaras's lack of knowledge about disease causation does not render him unqualified to opine on the adequacy of the warning label. To the contrary, based on his years of experience and academic credentials in human factors engineering, Dr. Samaras is qualified under Daubert to evaluate whether the warning on OTC Children's Motrin was sufficient to communicate the product's risks.

Dr. Samaras is also qualified to opine about whether Janet Leland would have continued to administer the ibuprofen to her daughter after the initial dose if the label had been different. Dr. Samaras is a certified professional ergonomist, with substantial experience studying how humans interact with product labeling. (Id. at 2, 21.) Defendants do not challenge his qualifications on this point, but instead challenge only whether his testimony fits the case. That argument is addressed below.

2. *Reliability*

Defendants are correct that Dr. Samaras's opinion about McNeil's "corporate priorities" is the product of unreliable methodology. Dr. Samaras's opinion appears to be based on his observations of the relative font sizes of the advertising and warning materials on the 1996 packaging for Children's Motrin, (see id. at 15), and the "well-known problem in human factors engineering, that folks in marketing and sales are focused on their function and not on other

functions." (Samaras Dep. at 62.)

This is an impermissibly thin basis on which to base an expert opinion. Dr. Samaras offers no evidence of misplaced priorities other than what jurors could observe themselves simply by looking at the Children's Motrin label. To the extent his opinion relies on such casual observations, Dr. Samaras would only be testifying about "lay matters which a jury is capable of understanding and deciding without the expert's help." In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d at 541 (citations omitted). Moreover, even assuming, arguendo, that it is a "well-known problem" that sales and marketing considerations dominate decision-making at drug companies, Dr. Samaras has cited to no research or data that supports his specific contention that McNeil's decision-making regarding Children's Motrin was inappropriately sales-and-marketing driven.

At base, Dr. Samaras's opinion about McNeil's priorities is nothing more than his subjective view about the company's behavior. Such testimony does not constitute "scientific, technical, or specialized knowledge" under Federal Rule of Evidence 702. Daubert, 509 U.S. at 590 ("[T]he word 'knowledge' connotes more than subjective belief or unsupported speculation."). Thus, it is insufficiently reliable and may not be admitted under Daubert.

On the other hand, the areas noted above about which Dr. Samaras is qualified to testify are the product of reliable methodology. His systematic review of relevant documents in this case provides a sound basis on which he can testify both about the need for and potential effects of a stronger warning. Thus, these opinions satisfy Daubert's reliability test.

3. *Fit*

Finally, the Court must assess whether Dr. Samaras's proposed testimony fits the case.

Plaintiff proposes to present testimony from Dr. Samaras that the FDA is under-resourced, and there is limited time for reviewers to do independent literature research. As a result, Dr. Samaras concludes that the reviewers rely heavily on the material submitted by the manufacturer.

The Court concludes that Dr. Samaras's general opinions about the functioning and funding of the FDA are not relevant to this case. His experiences in a vast federal agency with a multitude of different responsibilities is simply too generalized to have a "tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. The fact that Dr. Samaras had no direct involvement in the approval process for the Children's Motrin label involved in this case, (see Samaras Dep. at 147-49.), and has offered no specific opinions on the adequacy of that process, renders his testimony irrelevant. Thus, Dr. Samaras's proposed testimony about the general functioning and funding of the FDA does not fit the case.

On the other hand, there is no question that, as a general matter, testimony about the adequacy of the Children's Motrin label is central to and therefore fits the case. Defendants contend, however, that Dr. Samaras's opinion that Leland would have stopped giving plaintiff Children's Motrin after the first dose if the warning were more severe does not fit the case because "[n]othing in the factual record" supports the opinion that Leland would have heeded a different warning. (Defs.' Mot. to Exclude Samaras at 14.) As the Court stated in its Memorandum addressing defendants' motion for summary judgment, however, this is simply not the case. Leland testified in her deposition that even though she did not read the product's warnings when she first administered the drug to plaintiff, she turned to the label when plaintiff became ill:

> [L]ater during that week when I was getting just that motherly weird feeling that maybe this Motrin wasn't working good for her, I would study the box and the bottle just to see if there was anything on there that I should look for.

(Leland Dep. at 101:8-13.) There is sufficient support in the record for a reasonable jury to conclude that Leland would have heeded a different warning. Dr. Samaras's testimony about the potential effect of a different warning on Leland thus addresses a key issue in the case and, like his other opinions that are otherwise admissible, satisfies Daubert's fit requirement.[13]

4. *Conclusion*

Defendants' motion to exclude Dr. Samaras's testimony is granted in part and denied in part. Dr. Samaras will be allowed to testify that 1) the label on OTC Children's Motrin as of 1996 was inadequate because it did not warn of "rare but catastrophic dermatological and hepatic diseases" that could result from consuming the product and 2) a better warning would have caused Leland to stop administering the Children's Motrin to plaintiff. Dr. Samaras will not be allowed to testify that 1) the FDA's funding levels impede its ability to properly perform its duties, 2) ibuprofen is "dangerous" and "known to cause catastrophic illnesses," and 3) labeling of Children's Motrin was driven by McNeil's sales and marketing function.

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[13] To be sure, it ultimately will be up to the jury to determine whether a different warning would have convinced Leland to discontinue administration of the drug. However, the fact that Dr. Samaras is testifying to an "ultimate issue to be decided by the trier of fact" does not render his opinion objectionable. Fed. R. Evid. 704(a). Nor is his testimony barred because it aims to explain what would have happened in a counterfactual scenario. See Nesbitt v. Sears, Roebuck & Co., 415 F. Supp. 2d 530, 541-42 (E.D. Pa. 2005) (human factors expert allowed to testify about whether additional warning on saw would have been heeded if given); see also Lacayo v. Sodoma, 122 F.3d 1061 (Table), No. 97-1101, 1997 WL 583639, at *3 (4th Cir. Sept. 22, 1997) (holding that district court committed abuse of discretion by excluding testimony of fire expert who would have testified that presence of smoke detector would have prevented death).

V. Plaintiff's Daubert Motions

Plaintiff has moved to exclude the expert testimony of three of defendants' counter-causation experts: Drs. Maja Mockenhaupt, Margaret Fisher and Elizabeth Rand. The proposed testimony of all three experts deals with the nature and source of plaintiff's injuries and thus clearly satisfies Daubert's "fit" requirement. Moreover, plaintiff provides only a token challenge to Dr. Fisher's qualifications, noting that she does not consider herself an expert in SJS and VBDS. (Pl's Mot. to Preclude Fisher at 18.) As the Court has already ruled in the context of plaintiff's causation experts, however, an expert's base of knowledge need not be so specialized. See Section IV.A.1, supra. There is no question, as evidenced by the discussion of their backgrounds below, that Drs. Mockenhaupt and Rand are also qualified under Daubert.

Thus, all that remains is for the Court to assess whether each of the three experts' opinions is sufficiently reliable to be presented to the jury. The Court addresses each motion in turn.

A. Motion to Exclude Testimony of Dr. Maja Mockenhaupt

Dr. Mockenhaupt is a dermatologist from Germany. She has evaluated about 3,000 patients with SJS and related ailments in her career and has treated several hundred. (Mockenhaupt Dep. at 311-12.) Mockenhaupt has opined that:

- Kiley Wolfe likely suffered from something other than SJS (most likely a viral illness), though "a possible diagnosis of SJS . . . cannot be completely ruled out." (Mockenhaupt Report at 7.)
- Ibuprofen was likely not the source of plaintiff's illness. (Mockenhaupt Dep. at 357.)
- SJS can be caused by viral and bacterial infections. (Mockenhaupt Report at 9.)

Dr. Mockenhaupt, like the other causation experts in this case, based her opinions principally on a review of relevant documents provided to her.

Plaintiff asserts that Dr. Mockenhaupt's opinions should be excluded because (1) she has not reached an opinion, with a degree of medical certainty, on precisely what caused plaintiff's injuries and (2) her opinions are not the product of reliable processes. Neither argument is persuasive.

First, it is true that, under Pennsylvania law, plaintiff's causation experts must testify with reasonable medical certainty as to what caused plaintiff's injury for their opinions to be admissible. Paoli II, 35 F.3d 717, 750 (3d Cir. 1994). However, where defendant seeks to introduce evidence merely to cast doubt on the plaintiff's theory of causation, the expert need not definitively rule out plaintiff's theory for his testimony to be admitted. Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 786 (3d Cir.1996). This difference stems from the fact that plaintiff is the party with the burden of proving causation. Id. Thus, Dr. Mockenhaupt's testimony will not be excluded simply because she does not know to a reasonable degree of medical certainty what caused plaintiff's illness or from what illness plaintiff suffered.

Second, plaintiff contends that Dr. Mockenhaupt's proposed testimony that SJS can be caused by viral sources is insufficiently reliable because it is not based on epidemiological studies. As with plaintiff's experts, the use of case studies in informing Dr. Mockenhaupt's conclusion is not fatal. Moreover, Dr. Mockenhaupt's extensive experience treating patients with SJS provides a sufficient foundation for her to opine on the potential causes of the disease. Finally, the Third Circuit has never required citation to epidemiological studies for an expert opinion to be admissible, particularly where, as is the case with SJS and viral causes, no epidemiological study has ever been conducted. See Perry v. Novartis Pharm. Corp., 564 F. Supp. 2d 452, 465 (E.D. Pa. 2008).

In sum, the Court concludes that Dr. Mockenhaupt's opinions are reliable under Daubert and therefore admissible. Accordingly, plaintiff's motion to exclude her testimony is denied.

B. Motion to Exclude Testimony of Dr. Margaret Fisher

Dr. Margaret Fisher is a pediatric infectious diseases specialist practicing in New Jersey. Over the course of her career, she has both studied SJS and been involved in the treatment of children with SJS. (Fisher Dep at 153-54.) She has also determined the causes of SJS in patients as a part of her practice. (Id. at 154.) Based on her document review, she opined that:

- Plaintiff might have suffered from a viral infection, rather than SJS. (Id. at 71-72, 111.)
- Viral infections can cause SJS. (Id. at 153-55.)
- Even if plaintiff suffered from SJS, a viral cause cannot be ruled out. (Id. at 155.)
- Ibuprofen did not cause plaintiff's injuries. (Fisher Report at 4.)

Defendants make essentially the same challenges to Dr. Fisher's proposed testimony as to Dr. Mockenhaupt's. The result is the same, for the same reasons.

It is not necessary for a defense expert called to cast doubt on plaintiff's causation theory to reach a conclusion to a reasonable degree of medical certainty about what actually caused the injury. Holbrook, 80 F.3d at 786. Likewise, it is not necessary for an expert opinion to be based on an epidemiological study, particularly where none exists. Perry, 564 F. Supp. 2d at 465.

The Court concludes that Dr. Fisher's proposed testimony is sufficiently reliable under Daubert and is therefore admissible. Accordingly, plaintiff's motion relating to Dr. Fisher is denied.

C. Motion to Exclude Testimony of Dr. Elizabeth Rand

Dr. Rand is the Medical Director of the Liver Transplant Program at Children's Hospital of Philadelphia. (Rand Report at 1.) She has treated 10-20 patients with VBDS. (Rand Dep. at

29-30.) Based on her document review, she opined that:

- No specific cause of plaintiff's VBDS can be stated with medical certainty. (Rand Report at 5.)
- A viral infection may have caused plaintiff's VBDS. (Id. at 4.)
- It is "extremely improbable and implausible" that ibuprofen caused plaintiff's VBDS. (Rand Dep. at 56.)

Plaintiff again objects to the lack of medical certainty in Dr. Rand's opinions on causation, as well as the methodology by which she reached her conclusions. As with Drs. Mockenhaupt and Fisher, plaintiff's arguments are unpersuasive.

First, as noted above, a defense counter-causation expert need not reach a conclusion on causation to a medical certainty. Holbrook, 80 F.3d at 786. Second, Dr. Rand's extensive experience with patients with liver disorders and their causes, (see Rand Dep. at 29-30, 54, 211-12), and her review of documents pertinent to this case provide a reliable basis for her opinions.

The Court concludes that Dr. Rand's testimony is sufficiently reliable under Daubert and is therefore admissible. Accordingly, plaintiff's motion to exclude her testimony is denied.

VI. CONCLUSION

For the foregoing reasons, the Court denies defendants' motions to exclude the testimony of Drs. Arditi, Rosenthal and Chatila; defendants' motion to exclude the testimony of Buchanan and limit the testimony of Bunin; and plaintiffs' motions to exclude the testimony of Drs. Mockenhaupt, Fisher and Rand. Further, the Court grants defendants' motion to exclude the testimony of Drs. Goldberg and Bix as to Dr. Goldberg, and grants in part and denies in part the motion as to Dr. Bix. Finally, the Court grants in part and denies in part defendants' motion to exclude the testimony of Dr. Samaras. An appropriate order follows.